DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the General Counsel

Office of the Chief Counsel
Food and Drug Administration
5600 Fishers Lane, GCF-1
Rockville, MD 20857

October 27, 1999

Ms. Jennie Butler
Dockets Management Branch
HFA-305
Food and Drug Administration
5630 Fishers Lane
Rockville, MD 20852

Re: In re Rajaram K. Matkari
Docket No. 98N-0562

Dear Ms. Butler:

Enclosed please find the original and two copies of Stipulations and Admissions of Fact and Proposed Scheduling Order in the above case.

If you have any questions, please call me at 301-827-1138.

Very truly yours,

Annamarie Kempic
Associate Chief Counsel
for Enforcement

cc: Judge Davidson
Christopher B. Mead, Esq.

98N-0562

STP1

DEPARTMENT OF HEALTH AND HUMAN SERVICES
UNITED STATES OF AMERICA

In re	)	
	)	
RAJARAM K. MATKARI	)	FDA Docket No. 98N-0562
1304 Riverglen Way	)	
Berthoud, CO 80513	)	
	)	

Stipulations and Admissions of Fact
and Proposed Scheduling Order

Pursuant to the Order of the Administrative Law Judge, dated October 1, 1999, the parties submit the following stipulations as to the record in this case as well as to the authenticity of the documents in that record. In addition, the parties submit their stipulations and admissions of fact with respect to certain issues in this proceeding.

1. The parties stipulate to the following administrative record; the complete record is submitted with these stipulations.

A. Information.

B. Letter agreement dated December 5, 1988, to Hamilton P. Fox, III, Esquire, from Gary P. Jordan, First Assistant U.S. Attorney, signed by Rajaram Matkari and Hamilton P. Fox, III Esquire.

C. Judgment.

D. Statement of Facts.

E. October 20, 1993, Debarment Order, 58 FR 54156.

F. Articles of Incorporation Napean Enterprises, Inc.

G. Report of July 1997, Inspection of Sage Pharmaceuticals by Carolyn E. Barney, FDA Investigator.

H. March 31, 1997, Invoice No. 14893 from Akzo Nobel (Diosynth, Inc.) to Napean Enterprises for raw materials to be shipped to Sage Pharmaceuticals.

I. July 1997 handwritten customer lists and shipping instructions from Rajaram Matkari to Jack Antis, Pegasus Labs.

J. Aug. 12, 1997, memo from Joan S. Norton, FDA Consumer Safety Officer, to Keith Ehrlich, Supervisory Investigator, regarding Aug. 1997 inspection of Pegasus Laboratories.

K. February and May 1997 letters from Sage Pharmaceuticals to FDA regarding Sage ANDA.

L. Packing slip from Sage Pharmaceuticals for shipment to Pegasus Laboratories dated July 3, 1997, to be billed to Napean Enterprises.

M. Invoice 14893 from Akzo Nobel to Napean Enterprises for shipment of raw materials to Sage Pharmaceuticals and packing list.

N. Packing slips from Sage Pharmaceuticals for Napean's Menogen for shipment to various customers.

O. Feb. 15, 1996, an Agreement between Rajaram Matkari for Napean Enterprises, and Jivn-Ren Chen for Sage Pharmaceuticals.

P. Excerpt of Matkari's brief filed in support of his Motion to Strike certain portions of a Complaint filed by Sage

Pharmaceuticals Inc., against Napean Enterprises and Matkari, (Sage Pharmaceuticals v. Napean Enterprises, Civil No. 97-1983, W.D. Louisiana, Feb. 9, 1998), and denial of that motion, dated March 20, 1998.

Q. Summary Judgment Order entered in Florida Breckenridge, Inc. and Solvay v. Napean Enterprises Inc., (Civil No. 97-8417, S.D. Fla., March 18, 1998).

R. Court of Appeals opinion in Florida Breckenridge v. Solvay Pharmaceuticals, Civ. No. 98-4606 (11th Cir. May 11, 1999)(1999 WL 92667).

2. The parties stipulate to the authenticity of each of the documents identified in paragraph 1.

3. The parties stipulate to the following facts regarding the issues in this case.

A. Rajaram K. Matkari was debarred on October 20, 1993, from providing services in any capacity to a person with an approved or pending drug product application. Matkari reserves the right to contest the validity of the debarment based on the Sun Diamond case.

B. Napean Enterprises, Inc., is a Colorado corporation with Rajaram K. Matkari being its sole director.

C. Napean Enterprises Inc. was organized for the marketing of wholesale pharmaceutical products. Napean and Breckenridge do not own warehouse facilities and did not physically store or

distribute Menogen, but instead arranged for other entities to store and ship Menogen.

D. By letter dated February 15, 1996, Matkari on behalf of Napean Enterprises, entered an agreement with Sage Pharmaceuticals, by which Sage would manufacture for Napean Estratest and Estratest HS, known as Menogen.

E. On March 31, 1997, Matkari on behalf of Napean, purchased raw materials and had them shipped to Sage for use in manufacturing Menogen.

F. By the terms of the Feb. 12, 1996, agreement with Sage Pharmaceuticals, Napean, of which Matkari was the sole director, was responsible for all regulatory compliance for the marketing of the generic Estratest and Estratest HS, known as Menogen, and the agreement provided that Sage was responsible for all GMP practices during the manufacturing process of the tablets, that Sage was responsible for analytical method development and testing for the raw material and finished product, that Sage was responsible for packaging and labeling, and that Sage was responsible for quality control analysis, stability studies and any other listed requirements under the FDA regulations for GMP.

G. Sage had an abbreviated new drug application pending between February and June of 1997. At the time Matkari contracted with Sage for the manufacture of Menogen, Sage did not have any pending or approved ANDAs or NDAs, and he was not aware

that after Napean began its business relationship with Sage, that Sage applied for an ANDA. Once Sage filed its ANDA, it had its own responsibility under the debarment statute not to accept services from any debarred individuals.

H. Napean distributed the Menogen through a company know as Florida Breckenridge, Inc. (Breckenridge); many of the Sage invoices stated that Napean would receive payment for those shipments.

I. Breckenridge and the manufacturer of the related pioneer drug, Solvay, were involved in litigation based on various unfair trade practice and false advertising allegations. Napean was a counterclaim defendant in that lawsuit. Florida Breckenridge, Inc. and Solvay v. Napean Enterprises Inc., (Civil No. 97-8417, S.D. Fla., March 18, 1998).

J. The Court of Appeals for the Eleventh Circuit held that Menogen is an unapproved new drug. The Eleventh Circuit also held that Solvay's Estratest and Estratest H.S. were unapproved new drugs that had been marketed for over 30 years without any regulatory action by the FDA.

K. Napean and Matkari were also involved in commercial litigation with Sage Pharmaceuticals concerning the agreement to manufacture the Menogen. Sage Pharmaceuticals v. Napean Enterprises, Civil No. 97-1983, W.D. Louisiana, Feb. 9, 1998).

L. Napean and Matkari moved to strike the portions of Sage's Amended Complaint describing Matkari's debarment status; the district court denied that motion.

4. The parties agree to submit any limited discovery requests pertaining to outstanding issues by November 10, 1999, with responses due on December 10, 1999. The parties will submit any additional stipulations by December 17, 1999, or, if they are unable to stipulate to the few outstanding issues, a proposed schedule for the submission of written testimony and documentary evidence, and any additional motions such as motions to strike or for summary judgment. A proposed order is attached.

Respectfully submitted,

Annamarie Kempic
Counsel for the Center for
Drug Evaluation and Research

Christopher B. Mead (by AK)
Christopher B. Mead
Counsel for Respondent
Rajaram K. Matkari

CERTIFICATE OF SERVICE

I hereby certify that, on this 27th day of October, 1999, I have caused a copy of the foregoing Stipulations and Admissions of Fact and Proposed Scheduling Order to be served by first class mail on:

Mark London, Esq.
Christopher B. Mead, Esq.
London & Mead
1225 19th Street, N.W.
7th Floor
Washington, D.C. 20036

Annamarie Kempic

DEPARTMENT OF HEALTH AND HUMAN SERVICES
UNITED STATES OF AMERICA

In re	)	
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RAJARAM K. MATKARI	)	FDA Docket No. 98N-0562
1304 Riverglen Way	)	
Berthoud, CO 80513	)	
	)	

Order

On October 27, 1999, the parties to this proceeding submitted stipulations and admissions of fact as well as a proposed scheduling order for limited discovery. Accordingly, it is ordered that:

The parties will submit to each other any limited discovery requests pertaining to outstanding issues by November 10, 1999, with responses due on December 10, 1999.

The parties will submit any additional stipulations by December 17, 1999, or, if they are unable to stipulate to the few outstanding issues, a proposed schedule for the submission of written testimony and documentary evidence, and any additional motions such as motions to strike or for summary judgment.

Dated this _____ day of _____, 1999.

Daniel J. Davidson
Administrative Law Judge